

- Styrene (CAS No. 100–42–5).

We have received a request for a 60-day extension of the comment period for the petition. The request conveyed concern that the current 60-day comment period does not allow sufficient time to collect and provide data and information and develop a meaningful and thoughtful response to the assertions set forth in the petition.

We have considered the request and are extending the comment period for the petition for an additional 60 days, until May 3, 2016. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: February 18, 2016.

Dennis M. Keefe,

*Director, Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2014–N–1021]

Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: In the *Federal Register* of November 18, 2015, the Food and Drug Administration (FDA) published a proposed rule entitled “Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods.” The proposed rule would establish requirements concerning “gluten-free” labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. We are taking this action to reopen the comment period in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the proposed rule published November 18, 2015 (80 FR 71990). Submit either electronic or written comments by April 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2014–N–1021 for “Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including

the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carol D’Lima, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371, FAX: 301–436–2636.

SUPPLEMENTARY INFORMATION: The proposed rule would establish requirements concerning “gluten-free” labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These additional requirements for the “gluten-free” labeling rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as “gluten-free.” We provided a 90-day comment period for the proposed rule.

We received multiple requests for a 60-day extension of the comment period and one request for a 90-day extension of the comment period for the proposed rule. Each request conveyed concern that the original 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. We have considered the requests and are reopening the comment period for the

proposed rule until April 25, 2016. We believe that an additional 60-day period allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. The period for comments regarding information collection issues under the Paperwork Reduction Act of 1995 remains unchanged, where comments were to be submitted until February 22, 2016 (see 81 FR 3751, January 22, 2016).

Dated: February 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-129067-15]

RIN 1545-BM99

Definition of Political Subdivision

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that provide guidance regarding the definition of political subdivision for purposes of tax-exempt bonds. The proposed regulations are necessary to specify the elements of a political subdivision. The proposed regulations will affect State and local governments that issue tax-exempt bonds and users of property financed with tax-exempt bonds. Under certain transition rules, however, the proposed definition of political subdivision will not apply for determining whether outstanding bonds are obligations of a political subdivision and will not apply to existing entities for a transition period. This document also provides a notice of a public hearing for these proposed regulations.

DATES: Written or electronic comments must be received by May 23, 2016. Request to speak and outlines of topics to be discussed at the public hearing scheduled for June 6, 2016, at 10:00 a.m., must be received by May 23, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-129067-15), Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered to: CC:PA:LPD:PR Monday through Friday between the hours of 8

a.m. and 4 p.m. to CC:PA:LPD:PR (REG-129067-15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at www.regulations.gov (REG-129067-15). The public hearing will be held at the Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, Spence Hanemann at (202) 317-6980; concerning submissions of comments and the hearing, Oluwafunmilayo (Funmi) Taylor at (202) 317-6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to 26 CFR part 1 under section 103 of the Internal Revenue Code (Code). Section 103 generally provides that, with certain exceptions, gross income does not include interest on any obligation of a State or political subdivision thereof. Section 1.103-1 of the Income Tax Regulations (the Existing Regulations) defines political subdivision as "any division of any State or local governmental unit which is a municipal corporation or which has been delegated the right to exercise part of the sovereign power of the unit."

On a few occasions, Federal courts have ruled on whether an entity qualifies as a political subdivision. *E.g.*, *Philadelphia Nat'l Bank v. United States*, 666 F.2d 834 (3d Cir. 1981); *Comm'r of Internal Revenue v. White's Estate*, 144 F.2d 1019 (2d Cir. 1944). The IRS has also addressed this issue in revenue rulings, most recently in 1983. *E.g.*, Rev. Rul. 83-131 (1983-2 CB 184); Rev. Rul. 78-138 (1978-1 CB 314). Because the results in these revenue rulings generally turn on the unique facts and circumstances of the individual cases, numerous entities have sought and received letter rulings on whether they are political subdivisions. Letter rulings, however, are limited to their particular facts, may not be relied upon by taxpayers other than the taxpayer that received the ruling, and are not a substitute for published guidance. *See* 26 U.S.C. 6110(k)(3) (2015) (providing generally that a ruling, determination letter, or technical advice memorandum may not be used or cited as precedent).

Commenters have requested additional published guidance, to be applied prospectively, on which facts and circumstances are germane to an entity's status as a political subdivision.

The Treasury Department and IRS recognize the need to clarify the definition of political subdivision to provide greater certainty to prospective issuers and to promote greater consistency in how the definition is applied across a wide range of factual situations. These proposed regulations (the Proposed Regulations) would provide a new definition of political subdivision for purposes of tax-exempt bonds and would update and streamline other portions of the Existing Regulations. The definition of political subdivision in the Proposed Regulations does not apply in determining whether an entity is treated as a political subdivision of a State for purposes of section 414(d) of the Code.

Explanation of Provisions

1. Definition of Political Subdivision

The Proposed Regulations clarify and further develop the eligibility requirements for a political subdivision. To qualify as a political subdivision under the Proposed Regulations, an entity must meet three requirements, taking into account all of the facts and circumstances: sovereign powers, governmental purpose, and governmental control. The Proposed Regulations also authorize the Commissioner to set forth in future guidance to be published in the Internal Revenue Bulletin additional circumstances in which an entity qualifies as a political subdivision.

A. Sovereign Powers

The Proposed Regulations continue, without substantive change, the longstanding requirement that a political subdivision be empowered to exercise at least one of the generally recognized sovereign powers. The three sovereign powers recognized for this purpose are eminent domain, police power, and taxing power. *See Comm'r of Internal Revenue v. Shamburg's Estate*, 144 F.2d 998 (2d Cir. 1944). The entity must be able to exercise a substantial amount of at least one of these powers. *See, e.g.*, Rev. Rul. 77-164 (1977-1 CB 20); Rev. Rul. 77-165 (1977-1 CB 21).

B. Governmental Purpose

In determining whether an entity is a political subdivision, the case law and administrative guidance interpreting the definition of political subdivision in the Existing Regulations commonly consider whether the entity serves a public purpose. Historically, the determination of whether an entity serves a public purpose has focused on the purpose for which the entity was